

Dockets Management Branch (HFA-305) APR 24 09:49
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD. 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Signature

Date

March 19, 1999

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To Whom it May Concern:

I strongly oppose the draft M.O.U. being proposed by the FDA, particularly the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies. They are doing this not in the patient's best interest, but with the sole objective of making a profit. After 20 years of being in the minority of pharmacies with the patient's health their main concern, the FDA realizes special compounding pharmacies are doing a good job, and now they want to step in and take a piece of it for themselves. How childish!

Please do not let big bucks control everything; listen to your commonsense and your heart. After a difficult pregnancy, I spent two years going to over 20 doctors trying to figure out what was wrong with me. It took thousands of dollars not covered by insurance, and immeasurable energy, time and heartache. I had postpartum depression so severe that my daughter lived with my in-laws for five months. I was also hospitalized for one week. Each doctor or specialist couldn't get to the heart of the matter, and kept passing me to someone else. I read a large number of books, and ended up dealing with hormone specialists in both California and Colorado. The specialist in Colorado, Stephanie Bender, ordered saliva testing of my hormones, and we discovered that the levels were extremely low, with estrogen being in the post-menopausal range; I was only 32 years old. Since that time I have been on hormone replacement therapy, using a compounded progesterone cream from Madison Pharmacy Associates. I am getting better.

Because of all we have been through, we will not be having another child. I have finally found something that helps and I strongly urge you not to take this option away from me and many others like me. If I had not been able to get help, I don't know if I would be here today.
KEEP THINGS THE WAY THEY ARE!

Sincerely,

Jill Moniz

98N-1265

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Ms. Jill Moniz
11548 Chestfield Ct.
Orlando, FL 32837-5771



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ROCKVILLE, MD 20857